Variations in reporting of outcomes in randomised trials on diet and physical activity in pregnancy: a systematic review

Ewelina Rogozińska,[1,2] Nadine Marlin,[3] Fen Yang,[4] Jodie M. Dodd,[5,6] Kym Guelfi,[7] Helena Teede,[8] Fernanda Surita,[9] Dorte M. Jensen,[10] Nina R.W. Geiker,[11] Arne Astrup,[12] SeonAe Yeo,[13] Tarja I. Kinnunen,[14] Signe N Stafne,[15,16] Jose G Cecatti,[9] Annick Bogaerts,[17,18,19] Hans Hauner,[20] Ben W. Mol,[21] Tânia T Scudeller,[22] Christina A. Vinter,[23] Kristina M Renault,[24] Roland Devlieger,[25] Shakila Thangaratinam[1,2] Khalid S. Khan[1,2], for the i-WIP (International Weight Management in Pregnancy) Collaborative Group*

Running title: Outcomes & lifestyle trials in pregnancy

1. Women's Health Research Unit, Barts and the London School of Medicine and Dentistry, UK
2. Multidisciplinary Evidence Synthesis Hub (mEsh), Barts and the London School of Medicine and Dentistry, Queen Mary University of London, UK
3. Pragmatic Clinical Trials Unit, Barts and the London School of Medicine and Dentistry, Queen Mary University of London, UK
4. Human Reproduction, Shanghai Institute of Planned Parenthood and Reproduction, China
5. The Robinson Research Institute, Department of Obstetrics & Gynaecology, School of Medicine, The University of Adelaide, Australia
6. Women's and Children's Health Network, Women's and Babies Division, North Adelaide, Australia
7. Exercise Physiology and Biochemistry, The University of Western Australia, Australia
8. Monash Centre for Health Research and Implementation, School of Public Health, Monash University, Australia
9. Department of Obstetrics and Gynecology, School of Medical Sciences, The University of Campinas (UNICAMP), Brazil
10. Department of Endocrinology, Odense University Hospital, Denmark
11. Clinical Nutrition Research Unit, Nutrition Research Unit, Herlev and Gentofte Hospital,

The University of Copenhagen, Denmark

12. Department of Nutrition, Exercise and Sports, The University Copenhagen, Denmark
13. School of Nursing, The University of North Carolina at Chapel Hill, USA
14. School of Health Sciences, The University of Tampere, Finland
15. Department of Public Health and General Practice, Faculty of Medicine, Norwegian University of Science and Technology, Norway
16. Clinical Services, St. Olavs Hospital, Trondheim University Hospital Trondheim, Norway
17. Research Unit Healthy Living, University Colleges Leuven-Limburg, Belgium
18. Centre for Research & Innovation in Care, University of Antwerp, Belgium
19. Department Development and Regeneration, KU Leuven, Belgium
20. Center for Nutritional Medicine, Technische Universität München, Germany
21. The South Australian Health and Medical Research Institute, Australia
22. Department of Management and Health Care, São Paulo Federal University (UNIFESP), Brazil
23. Department of Obstetrics and Gynecology, Odense University Hospital, The University of Southern Denmark, Denmark
24. Department of Obstetrics and Gynecology, Hvidovre Hospital, University of Copenhagen, Denmark
25. Division of Mother and Child, Department of Obstetrics and Gynaecology, University Colleges Leuven-Limburg, Hasselt and University Hospitals KU Leuven, Leuven, Belgium

Corresponding author:

Ms. Nadine Marlin

Pragmatic Clinical Trials Unit, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, 58 Turner Street, London E1 AB

Email: n.marlin@qmul.ac.uk

Tel: +44 20 7882 7327

Word count of the main text: 2,556

Abstract

Aim

Trials on diet and physical activity in pregnancy report on various outcomes. We aimed to assess the variations in outcomes reported, and their quality in trials on lifestyle interventions in pregnancy.

Methods

We searched major databases up to March 2015 without language restrictions for randomised controlled trials (RCTs) on diet and physical activity-based interventions in pregnancy. Two independent reviewers undertook study selection and data extraction. We estimated the percentage of papers reporting ‘critically important’ and ‘important’ outcomes. We defined the quality of reporting as a proportion using a 6-item questionnaire. The regression analysis was used to identify factors affecting this quality.

Results

Sixty-six RCTs were published in 78 papers (66 main, 12 secondary). Gestational diabetes (57.6%, 38/66), preterm birth (48.5%, 32/66) and cesarian section (60.6%, 40/66), were the commonly reported ‘critically important’ outcomes. Gestational weight gain (84.5%, 56/66) and birth weight (87.9%, 58/66), were reported in most papers, although not ‘critically important’. The median quality of reporting was 0.60 (IQR 0.25, 0.83) for a maximum score of one. Study and journal characteristics did not affect the quality.

Conclusion

Many studies on lifestyle interventions in pregnancy do not report ’critically important’ outcomes, highlighting the need for core outcome set development.

Keywords: Outcomes, quality, randomised trials, diet, physical activity, pregnancy

Word count: 198

Introduction

Many randomised trials have evaluated the effects of diet and physical activity based interventions in pregnancy on maternal and fetal outcomes. [1-3] The main aim of these studies is to minimise morbidity and mortality. Given the relatively small number of severe complications, systematic reviews and meta-analysis are crucial to synthesise evidence from individual studies to provide robust estimates with precision. Selective reporting of trial results can seriously impair evidence synthesis, and its usefulness to inform clinical practice. [4] Trials on diet and physical activity in pregnancy involve a multidisciplinary team of researchers from varied backgrounds such as obstetricians, dieticians, kinesiology, health psychologists and economists, midwives, scientists, and epidemiologists. This may have an impact on the choice of primary and secondary outcomes.

The International Weight Management in Pregnancy (i-WIP) Network comprising of researchers in the above areas has prioritised the importance of various maternal and fetal outcomes for clinical care. The proportion of published studies that have reported the prioritised outcomes is not known. The CONsolidated Standards Of Reporting Trials (CONSORT) statement was introduced to standardise and improve reporting of RCTs and became a part of submission requirements for a number of medical journals. [5-7] Its impact on quality of reports on diet and lifestyle based trials is not known. The quality of the reported outcomes is affected by various factors specific to the study or to the journal in which it is published. [8, 9] There is a need to assess the variation in reporting of outcomes in trials on diet and lifestyle, and their quality.

We undertook a systematic review to evaluate the differences in reporting ‘critically important’ and ‘important’ maternal and fetal outcomes in studies on diet and physical activity-based interventions in pregnancy, the quality of reporting, and to assess the association of outcome reporting quality with study related and journal related factors.

Materials and methods

The systematic review was undertaken with a prospective protocol in accordance with currently accepted methods [10, 11] and reporting standards (PRISMA statement) [12].

Search strategy and study selection

We updated the search strategy that was undertaken for our previous systematic review on effects of diet and physical activity interventions in pregnancy [13]. The search was conducted in the CENTRAL, EMBASE, MEDLINE, Centre for Reviews and Dissemination, and the Cumulative Index to Nursing & Allied Health Literature (CINAHL) databases without any language limits. The search strategy can be found in Appendix 1. We searched for randomised controlled trials (RCTs) with weight management interventions targeting diet and physical activity compared to routine care. The systematic search of databases was supplemented by the reference and hand search.

Two reviewers (ER, FY) independently assessed the titles and abstracts, and the full texts of potentially relevant papers. We included randomised controlled trials with pregnant women evaluating the effect of diet, physical activity or a combination of both on pregnancy outcomes. We excluded studies on women with gestational or pre-pregnancy diabetes, trials reporting only change in the consumption of particular food products, protocols, conference abstracts and studies published before 1990. Any disagreements on the eligibility of included studies, at any stage, was resolved by a third reviewer (ST).

Quality assessment and data extraction

Study and outcome quality assessment (ER and NM), and data extraction (ER and FY) were undertaken independently by two reviewers. The quality of RCTs was assessed using a domain-based the Cochrane risk of bias [14]. The quality of describing and reporting outcomes was

evaluated using a 6-item questionnaire as presented by Harman et al. [15]. The points were assigned in the following manner: primary outcome clearly stated (1-point), if outcome stated its definition was given (1-point); secondary outcome(s) listed (1-point), if reported their clear definition was given (1-point); explanation of the outcomes use in statistical analysis (1-point) and description of methods to enhance quality of measures (1-point). When primary or secondary outcomes were not clearly stated we did not assess how well they were defined (not applicable status). We defined the quality of outcome reporting score as the proportion of points out of a maximum of 6 points.

We categorised all identified outcomes as 'critically important', 'important' or 'not important' in the management of maternal weight in pregnancy using findings of two-stage Delphi survey. 20 clinicians interested in the field were asked to rank importance of 31 maternal and 27 fetal outcomes identified through systematic review or add other ones. The median and IQR of responses defined the importance of outcomes. [13] The journals were classified as general vs. specialist journals, and as obstetrics focused vs. other specialities (dieticians, physical activity experts, etc.). Where possible we retrieved an impact factor of the journal in the given publication year (The Thomson Reuters) [16], the most commonly used marker in science citation.

Data synthesis

We calculated the proportion of papers on diet, physical activity and mixed interventions that reported outcomes categorised as 'critically important', and 'important', which were scored for their importance to clinical practice. The quality of outcome reporting score per published article was the proportion of the assigned points on the 6-item questionnaire (as above), and non-applicable items were considered as missing values. All continuous data were examined for non-linearity and log transformed, if necessary. Initially, we explored the association of outcome quality score with study quality and journal characteristics such as journal impact factor and

year of publication using Spearman's rank correlation. Year of publication was also dichotomized to assess whether the quality of outcome reporting was different between the studies published before and after the update of CONSORT statement in 2010 [5](the cut-off year 2011). The relationship between the pre-specified variables (journal type, impact factor, publication year, and risk of bias items), and outcome quality score was quantified using multiple linear regression models with a bootstrapping sampling method (1000 iterations, with a set seed) to allow for skewness in the outcome data.[17] To identify important factors in the multivariable analysis of outcome quality score, we applied a backwards stepwise approach to the full list of factors considered (p-value threshold p=0.2). Categorical variables were considered for exit based on the category with the lower p-value. We undertook sensitivity analyses to assess the impact of using alternative approaches to variable selection and calculating quality of outcome reporting score, as well as including trials not powered for the clinical outcomes reported (feasibility or pilot studies). For categorical variables, we performed global post-estimation tests (Wald tests) to present overall significance of a categorical factor. All methods were defined a priori except for the dichotomization of the year of publication to pre and post CONSORT 2010. Analyses were performed using STATA version 12.1.[18] Statistical significance was considered at the 5% level.

Results

Characteristics of included studies

From 3,551 potential citations identified, we included 66 trials published in 78 papers (66 primary trial reports and 12 publications with secondary analyses) (Figure 1). The publications with secondary analyses came from ten trials and were published one year later than the primary report. The primary publications in 44% of the cases (29/66) were published in obstetrics journals with the majority published after the introduction of CONSORT statement in 1996, and more than half (40/66, 60.6%) after CONSORT update in 2010 (Figure 2). The median impact factor in this cohort of studies was 3.04 (IQR 1.50, 4.39) with a range of 0 to 17 (Appendix 2

and 3). The intervention in 12 trials was diet-based, in 23 a mixed (diet and physical activity) approach, and 31 only physical activity (Appendix 3). In comparison to the trials' primary publications, subsequent publications had a lower impact factor but a comparable quality of outcome reporting.

Variation in reported outcomes

The trials on diet and lifestyle interventions in pregnancy reported 142 outcomes, with half of them (72/142, 50.7%) appearing in the evaluated publications only once. For example, women's anxiety was reported as an outcome in only one trial. The median number of outcomes per trial was 12 (IQR 8, 15), with mixed approach trials reporting more outcomes per trial (median 13, IQR 10, 18). A previous Delphi ranking of researchers and clinicians had classified 22 outcomes as 'critically important' and 23 as 'important' to clinical care in the 142 outcomes identified in this evaluation. In outcomes ranked to be 'critically important', the commonly reported outcomes were a cesarean section (40/66, 60.6%) followed by gestational diabetes mellitus (GDM) (38/66, 57.6%) and preterm birth (32/66, 48.5%). Of the 'important' outcomes, gestational weight gain (56/66, 84.5%), infant birth weight (58/66, 87.9%) and Apgar score (32/66, 48.5%) were frequently reported (Table 1). There was no significant difference in the proportion of 'critically important' or 'important' outcomes reported by studies mainly on diet, physical activity or mixed approach (Pearson Chi2, p=0.111). A detailed list of items not covered by the Delphi ranking can be found in Appendix 4.

Quality of outcome reporting

The primary outcome was clearly stated in over a half of the articles (39/66 primary publications), and if reported, described in a reproducible way in most of the cases (34/39, 87.2%). The outcomes were described as 'secondary' in 42% of assessed primary publications (28/66), with 20 of 28 (71.4%) providing clear definitions for their reproducibility. Authors gave an explanation of statistical methods used to analyse outcomes in 48 publications (72.7%)

and mentioned any method of improving the outcome measure's quality in one-third (22/66, 33.3%) of the evaluated primary publications (Figure 3). The median quality of outcome reporting score was 0.60 (IQR 0.25, 0.83) for a maximum score of one. Comparison of the trials published before and after update of CONSORT guidelines in 2010 showed a significant difference in the quality of outcome reporting between two groups (Wilcoxon rank sum test, $p<0.01$) (Appendix 2).

Factors influencing outcomes' quality

In univariate analysis, there was a significant positive correlation between outcome quality score ($p<0.05$) and publication features such as year of publication, and the journal's impact factor; outcome quality score was also negatively correlated with allocation concealment and attrition bias ($p<0.05$). None of the factors considered in the multivariate regression model showed a statistically significant association with quality of outcome reporting (Table 2).

Discussion

Main findings

Trials of diet and physical activity-based interventions in pregnancy report a variety of maternal and fetal outcomes. 'Critically important' outcomes such as gestational diabetes or caesarean section were reported less often compared to 'non-critical' ones such as gestational weight gain or birth weight. The overall quality of outcome reporting varied between trials and was particularly low for reporting on methods to improve outcome measures. The quality of reported outcomes was not found to be influenced by study or journal-specific factors.

Strengths and limitations

Our work comprehensively evaluates the diversity and quality of outcome reporting in trials on diet and physical activity-based interventions in pregnancy. We used existing ranking of outcomes for their importance to assess the relevance of reported outcomes. In our work, we

followed the established standards for evidence synthesis. [10, 11] This systematic review was conducted with no language limits and gives a thorough overview of international research. The identification of relevant publications was made through a systematic database search, the study quality assessed using Cochrane risk of bias [14], and two independent researchers executed all steps of the review. In the areas where there are no formal guidelines (quality of outcome reporting), we adhered to principles of conduct of rigorous scientific research and the impact of all the assumptions was explored through a set of a priori defined sensitive analyses.

Although, we limited our studies to only those published after 1990 the majority of trials evaluating the effect of diet and physical activity-based intervention in pregnancy were published in the last two decades. Classification of the outcomes according to their importance to weight management during pregnancy was based on a Delphi ranking conducted among clinicians with the interest in the subject. A different panel may have identified a different set of prioritised outcomes. However, the majority of the most frequently reported outcomes were captured by the survey and ranked as 'critically important' or 'important' to women's care.

We used the questionnaire by Harman et al. [15] to assess the quality of outcome reporting, which was used in other reviews to assess variation and quality of outcomes. Application of this questionnaire has certain limitations. For example, the questionnaire does not take into account secondary analyses from the original trials or that the description of primary or secondary outcomes cannot be assessed if outcomes in the trial reports are not clearly stated. For future work on the quality of outcome reporting, more objective and less ambiguous tools should be developed to assess the quality of outcome reporting from clinical trials.

Interpretation

Research, to guide and influence clinical practice and policy development, needs to provide evidence on the effects of interventions on the outcomes relevant to all relevant stakeholders.

The range of outcomes reported in evaluated trials reflects the range of specialities examining the effect of diet and physical activity-based interventions on maternal and fetal well-being.

The most commonly reported outcomes are routinely collected, surrogates for maternal and neonatal morbidity (gestational weight gain and birthweight). None of the 'critically important' maternal or infant related outcomes had comparable reporting coverage as above two surrogates. Even though information allowing to compute outcomes such preterm birth or giving birth to the small-for-gestational-age infant (birthweight and gestational age at birth) were appeared in the majority of publications.

Reproducibility is a core principle of any scientific research. The rationale behind CONSORT requirement for reporting of primary and secondary outcomes is to allow other researchers to use the same outcomes. [19] Basing on the reporting of primary publications, it would not be possible to reproduce the primary outcome for more than one-third of cases. The reporting of secondary outcomes was insufficient in over half of publications. Furthermore, the weakest aspect of outcome was the scarce availability of information about the collection of outcome measurements. This might not affect outcomes such as cesarean section or occurrence of birth trauma but may additionally weaken the reliability of the outcomes where thorough training and repeated measurements play a significant role (high blood pressure, pre-eclampsia).

In contrast to the findings of other studies in the area of obstetrics and gynaecology, the quality of outcome was not linked to any of the publication or journal features. [8, 9] The *posthoc* comparison of studies published before and after of the CONSORT statement in 2010 seems to show an improvement in outcomes reporting post CONSORT most recent update. However, publication year and the quality of outcome reporting score did not show any association when adjusting for other journal and publication features.

Issues identified in our study are not limited to trials of lifestyle interventions or the field of obstetrics and gynaecology research. Variation in outcome reporting and use of multiple measures are highlighted as a hindrance to research informing clinical practice [20] regardless of medical specialities [21-25].

Recommendations

More effort should be invested to improve the communication between the medical specialities conducting trials with diet and physical activity. This could be achieved through development and introduction of a core outcome set (COS), a minimum set of outcomes that should be collected and reported alongside other outcomes of research interest. [20, 26] This concept developed by the COMET Initiative has been embraced by the researchers and the editors of obstetrics and gynaecology journals. [27] The CROWN (CoR Outcomes in WomeN's health) initiative recognizes the limitations imposed by the variation in reporting of outcomes and promotes COS as a way to improve the evidence synthesis and to draw more meaningful conclusions. It has been shown in the case of rheumatoid arthritis trials that introduction of COS leads to improvement of the consistency of outcome reporting [28].

Our work has highlighted the wide variation, and limited reporting of clinically important outcomes in trials on diet and physical activity in pregnancy. The quality of outcome reporting needs to be improved. Development of a core outcome set to be minimally reported in studies on this topic, with standardisation of measurements will facilitate robust evidence synthesis.

Acknowledgement

We thank the EBM-CONNECT (Evidence-based medicine collaboration: network for systematic reviews and guideline development research and dissemination) Collaboration, in alphabetical order by country: L. Mignini, Centro Rosarino de Estudios Perinatales, Argentina;

P. von Dadelszen, L. Magee and D. Sawchuck, University of British Columbia Canada; E. Gao, Shanghai Institute of Planned Parenthood Research, China; B.W. Mol and K. Oude Rengerink, Academic Medical Centre, the Netherlands; J. Zamora, Ramon y Cajal, Spain; C. Fox and J. Daniels, University of Birmingham, UK; K.S. Khan, S. Thangaratinam, and C. Meads, Barts and the London School of Medicine, Queen Mary University of London, UK.

*i-WIP Collaborative Group: Arne Astrup, Ruben Barakat, Annick Bogaerts, Jose G Cecatti, Jodie M. Dodd, Arri Coomarasamy, Roland Devlieger, Nermean El Beltagy, Fabio Facchinetti, Nina R.W. Geiker, Kym Guelfi, Lene A.H. Haakstad, Cheryce Harrison, Hans Hauner, Dorte M. Jensen, Tarja I Kinnunen, Khalid S. Khan, Janette Khoury, Riitta Luoto, Ben Willem Mol, Siv Mørkved, Narges Motahari, Fionnuala McAuliffe, Julie Owens, Maria Perales, Elisabetta Petrella, Suzanne Phelan, Lucilla Poston, Mireille van Poppel, Kathrin Rauh, Girish Rayanagoudar, Kristina Renault, Ewelina Rogozińska, Anneloes Ruifrok, Linda R Sagedal, Kjell A. Salvesen, Tânia T. Scudeller, Gary X. Shen, Alexis Shub, Signe N. Stafne, Fernanda Surita, Helena Teede, Shakila Thangaratinam, Serena Tonstad, Christina A. Vinter, Ingvild Vistad, Marcia Vitolo, Seonae Yeo.

Conflict of interest

The authors declare that there is no conflict of interests.

References

1. Muktabhant B, Lawrie TA, Lumbiganon P, Laopaiboon M. Diet or exercise, or both, for preventing excessive weight gain in pregnancy. The Cochrane database of systematic reviews. 2015;6:Cd007145.
2. Oteng-Ntim E, Varma R, Croker H, Poston L, Doyle P. Lifestyle interventions for overweight and obese pregnant women to improve pregnancy outcome: systematic review and meta-analysis. BMC Med. 2012;10:47.
3. Thangaratinam S, Rogozinska E, Jolly K, Glinkowski S, Roseboom T, Tomlinson JW, et al. Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence. BMJ. 2012;344:e2088.
4. Chan AW, Altman DG. Identifying outcome reporting bias in randomised trials on PubMed: review of publications and survey of authors. Bmj. 2005;330(7494):753.
5. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ. 2010;340:c332.
6. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA. 1996;276(8):637-9.
7. Moher D, Schulz KF, Altman D, Group C. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. JAMA. 2001;285(15):1987-91.
8. Hirsch M, Duffy JM, Kusznir JO, Davis CJ, Plana MN, Khan KS, et al. Variation in outcome reporting in endometriosis trials: a systematic review. Am J Obstet Gynecol. 2016;214(4):452-64.
9. Tirlapur SA, Ni Riordain R, Khan KS, Collaboration E-C. Variations in the reporting of outcomes used in systematic reviews of treatment effectiveness research in bladder pain syndrome. Eur J Obstet Gynecol Reprod Biol. 2014;180:61-7.
10. Higgins JPT GSe. Cochrane Handbook for Systematic Reviews of Interventions: The Cochrane Collaboration; 2011. Available from: cochrane-handbook.org.
11. Khan KSK, R.; Kleijnen, J., Antes, G. . Systematic reviews to support evidence-based medicine: how to review and apply findings of healthcare research. 2nd ed. London (UK): Hodder Arnold; 2011.
12. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. Bmj. 2009;339:b2700.
13. Thangaratinam S, Rogozinska E, Jolly K, Glinkowski S, Duda W, Borowiack E, et al. Interventions to reduce or prevent obesity in pregnant women: a systematic review. Health Technol Assess. 2012;16(31):iii-191.
14. Higgins JPTA, D.G. . Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT GS, editor. Cochrane Handbook for Systematic Reviews of Interventions. Chichester (UK): John Wiley & Sons; 2008.
15. Harman NL, Bruce IA, Callery P, Tierney S, Sharif MO, O'Brien K, et al. MOMENT--Management of Otitis Media with Effusion in Cleft Palate: protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey. Trials. 2013;14:70.
16. Reuters T. The Thomson Reuters Impact Factor 2015 [updated 2015. Available from: http://wokinfo.com/essays/impact-factor/.
17. Thompson SG, Barber JA. How should cost data in pragmatic randomised trials be analysed? BMJ. 2000;320(7243):1197-200.
18. StataCorp. Stata Statistical Software. 12.1 ed: College Station, TX: StataCorp LP. 2015.; 2015.
19. Glasziou P, Meats E, Heneghan C, Shepperd S. What is missing from descriptions of treatment in trials and reviews? Bmj. 2008;336(7659):1472-4.

20. Williamson PR, Altman DG, Blazeby JM, Clarke M, Devane D, Gargon E, et al. Developing core outcome sets for clinical trials: issues to consider. Trials. 2012;13:132.
21. Benstoem C, Moza A, Autschbach R, Stoppe C, Goetzenich A. Evaluating outcomes used in cardiothoracic surgery interventional research: a systematic review of reviews to develop a core outcome set. PLoS One. 2015;10(4):e0122204.
22. Kapadia MZ, Joachim KC, Balasingham C, Cohen E, Mahant S, Nelson K, et al. A Core Outcome Set for Children With Feeding Tubes and Neurologic Impairment: A Systematic Review. Pediatrics. 2016;138(1).
23. Marks M, Schoones JW, Kolling C, Herren DB, Goldhahn J, Vliet Vlieland TP. Outcome measures and their measurement properties for trapeziometacarpal osteoarthritis: a systematic literature review. J Hand Surg Eur Vol. 2013;38(8):822-38.
24. Opondo D, Gravas S, Joyce A, Pearle M, Matsuda T, Sun YH, et al. Standardization of patient outcomes reporting in percutaneous nephrolithotomy. J Endourol. 2014;28(7):767-74.
25. Whitehead L, Perkins GD, Clarey A, Haywood KL. A systematic review of the outcomes reported in cardiac arrest clinical trials: the need for a core outcome set. Resuscitation. 2015;88:150-7.
26. Clarke M. Standardising outcomes for clinical trials and systematic reviews. Trials. 2007;8:39.
27. Khan K. The CROWN Initiative: journal editors invite researchers to develop core outcomes in women's health. BJOG. 2014;121(10):1181-2.
28. Kirkham JJ, Boers M, Tugwell P, Clarke M, Williamson PR. Outcome measures in rheumatoid arthritis randomised trials over the last 50 years. Trials. 2013;14:324.

Tables *(in separate files)*

Table 1 ‘Critically important’ and ‘important’* outcomes reported in trials (N = 66) of diet and physical activity-based interventions in pregnancy

Table 2 Association between study and publication factors with quality of outcome reporting in trials with diet and physical activity-based interventions in pregnancy, N = 66

Figures *(in separate files)*

Figure 1 Study selection flow diagram with number of identified outcomes

Figure 2 Number of publications per year

Figure 3 Quality of outcome reporting in trials with diet and physical activity-based interventions in pregnancy

Supplementary Material

Appendix 1 Search strategy for identification of randomised trials on lifestyle interventions in pregnancy and maternal and offspring outcomes

Appendix 2 Summary descriptive of characteristics evaluated in the study

Appendix 3 Detailed characteristic of included papers

Appendix 4 List of measured outcomes reported in articles from trials with diet and physical activity interventions in pregnancy not covered by the Delphi ranking